

--89. (new) A syringe for the parenteral injection of a semi-solid formulation, comprising:

a hollow reservoir, prefilled with a semi-solid preparation to be injected;

a piston for pressing against the semi-solid preparation to be injected;

a needle opening to said reservoir; and

a housing surrounding an entirety of said reservoir,

wherein an internal surface of said housing slidably engages an external surface of said reservoir along an entirety of said external surface.--

Please charge the fee of \$18 for the one extra claim of any type added herewith to Deposit Account No. 25-0120.

REMARKS

The specification has been amended to make editorial changes to place the application in condition for allowance at the time of the next Official Action.

A substitute Abstract of the Disclosure is provided on an accompanying separate sheet.

Claims 44-86 were previously pending in the application. Claims 44 and 48 are cancelled and new claims 87-89 are added. Therefore, claims 45-47 and 49-89 are presented for consideration. Claims 56 and 58-86 are withdrawn from consideration as being drawn to a non-elected species.

Claim 45 is amended to address the 35 USC §112, second paragraph rejection noted in the Official Action.

Claims 44-50 and 52 are rejected as anticipated by YAMASHITA JP 55073352.

Reconsideration and withdrawal of the rejection are respectfully requested because the reference does not disclose or suggest that a support or casing forms a peripheral shell surrounding an external surface of the element forming a reservoir with virtually zero clearance as recited in claim 45 of the present application.

By way of example, page 13, lines 4-7 of the present application in conjunction with Figure 1 disclose that the casing element 7 is provided with a central passage having a diameter approximately identical to the internal diameter of the tube.

In contrast, as seen in Figure 1 of YAMASHITA, for example, a substantial gap is between the main cylinder body 11 and the holder 17 to compensate for thermal expansion and contraction due to the change of temperature. YAMASHITA requires this gap because the main cylinder body 11 made of glass would crack without an expansion gap between the main cylinder body 11 and the holder 17. Such an expansion gap does not provide virtually zero clearance. Accordingly, YAMASHITA does not disclose or suggest a peripheral shell surrounding an external surface of the element forming a reservoir with virtually zero clearance as recited in claim 45 of the present application. As

the reference does not disclose that which is recited, the anticipation rejection is not viable. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 46-50 and 52 depend from claim 45 and further define the invention and are also believed patentable over YAMASHITA.

Claims 44-55 and 57 are rejected as unpatentable over YAMASHITA in view of SHAPIRO 4,165,646. This rejection is respectfully traversed.

SHAPIRO is only cited for the teaching of a reservoir having two tubes as recited in claim 57 of the present application. SHAPIRO does not teach or suggest what is recited in claim 45. As noted above, YAMASHITA does not disclose or suggest what is recited in claim 45. Accordingly, the combination of references would not render obvious claim 57.

Claims 51-55 are also believed patentable over YAMASHITA in view of SHAPIRO based on their dependency from claim 45.

In addition, as seen in Figure 1 of SHAPIRO, for example, the reservoir of SHAPIRO is element 34. Piston 35 provides suction so that liquid can be admitted into reservoir 34 and expelled by the downward movement of piston 35. Each of the elements above element 39 in Figure 1 of SHAPIRO form part of a calibrating device. As disclosed on column 3, lines 1-17 of SHAPIRO, the calibrating device is detachably locked into

engagement on an annular groove of bushing 31. Accordingly, SHAPIRO does not teach that for which it is offered. Specifically, SHAPIRO teaches a reservoir 34 having a single tube, not a tubular reservoir consisting of two or more tubes, one placed behind the other as recited in claim 57 of the present application.

Claims 44 and 45 are rejected as anticipated by PITESKY 4,008,718. This rejection is respectfully traversed.

PITESKY was not applied against claim 48. Since the subject matter of claim 48 was added to claim 45, claim 45 is believed patentable over PITESKY.

In addition, PITESKY teaches a cylindrical barrel B (reservoir) and a piston F in the barrel B. A lower end of the barrel B has a cap C which only surrounds a lower extremity of the barrel and is not a casing that forms a shell that surrounds the external surface of the element forming the reservoir as recited in claim 45. In addition, PITESKY teaches seal 86 located between the cap and the barrel to form a gap therein.

New claim 87 recites that the external surface of the reservoir is directly contacting the casing. New claim 88 recites that an entirety of the external surface contacts an internal surface of the casing. New claim 89 also recites that the external surface of the reservoir contacts the cylindrical surface of the casing. The comments above regarding claim 45 are equally applicable to new claims 87-89. Accordingly, it is

believed that the new claims avoid the rejections under §102 and §103 and are allowable over the art of record.

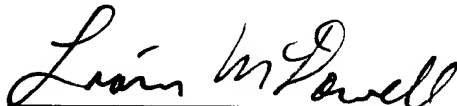
In the Official Action of July 23, 2002, claim 45 was indicated as generic. Since claim 45 is generic and believed allowable, claims 56 and 58-86 should be examined and allowed.

In view of the present amendment and the foregoing remarks, it is believed that the present application has been placed in condition for allowance. Reconsideration and allowance are respectfully requested.

Attached hereto is a marked-up version showing the changes made to the abstract, specification and claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

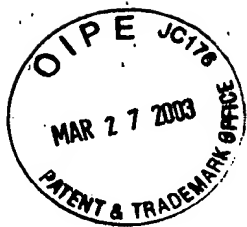
YOUNG & THOMPSON

By 
Liam McDowell
Attorney for Applicants
Registration No. 44,231
745 South 23rd Street
Arlington, VA 22202
Telephone: 703/521-2297

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ABSTRACT OF THE DISCLOSURE

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A syringe for parenteral injection of a semi-solid formulation. The syringe includes a hollow element forming a reservoir for the semi-solid product to be injected between a plunger and a needle hub urged in contact with the reservoir end. The plunger comes into direct contact with the hub when the dose contained in the reservoir-forming element has been injected. The element forming a reservoir and the needle are maintained mutually interlocked at the hub through a mount or case receiving the element forming a reservoir.



CHERIF CHEIKH et al. S.N. 09/787,508

"VERSION WITH MARKINGS TO SHOW CHANGES MADE"

ABSTRACT OF THE DISCLOSURE

The Abstract of the Disclosure has been amended as follows:

[The invention concerns a] A syringe for parenteral injection of a semi-solid formulation[, comprising]. The syringe includes a hollow element [(1)] forming a reservoir for the semi-solid product to be injected between a plunger and a needle [(3)] hub [(4)] urged in contact with the [said] reservoir [(1)] end[, such that the]. The plunger [(2)] comes into direct contact with [said] the hub [(4)] when the dose contained in [said] the reservoir-forming element has been injected[, said]. The element forming a reservoir [(1)] and [said] the needle [(3)] are maintained mutually interlocked at [said] the hub through a mount or case [(5,7)] receiving [said] the element forming a reservoir [(1)].

IN THE SPECIFICATION:

Page 15, the paragraph, beginning on line 6, has been amended as follows:

--Figure 2 shows that the piece 7 need only be replaced with a cup-shaped piece 13 which can be screwed in the same way onto the end of the casing element 5 and which is provided with a tapped passage 14 into which a threaded piston rod [5] 15 can be screwed. All that is then required is to rotate the threaded rod

15 in order for it to move in the tube 1 and, consequently, for the thrust of the piston 2 to expel the formulation. Such gearing-down can easily allow forces of the order of 200 N to be deployed. Moreover, the screw pitch also makes it possible to administer only part of the dose, and in a precise manner by virtue of a graduated scale.--.

Page 16, the paragraph, beginning on line 35, bridging pages 16 and 17, has been amended as follows:

--Figure 7 shows another embodiment in which, in order to have a small volume of formulation using a large-diameter tube 1, it is the base 32 of the needle [3] 33 which extends over a great distance inside the tube 1 in order to form the reservoir proper, filled with the preloaded formulation. The piston may, for example, be made in the form of a metal rod 34 emerging in the tube 1 and passing through a septum 35 which holds it in place.--.

IN THE CLAIMS:

Claim 45 has been amended as follows:

--45. (amended) A prefilled syringe intended for the parenteral injection of a semi-solid formulation, comprising a hollow element [(1)] forming a reservoir, prefilled with [the] a semi-solid preparation to be injected between a piston and a base [(4)] of a needle [(3)] which comes into contact with one end of said reservoir [(1)], so that the piston [(2)] comes into direct

contact with said base [(4)] for the purpose of injecting the dose contained in said element forming a reservoir, said element forming a reservoir [(1)] and said needle [(3)] being held fastened to each other at said base, by a support or casing [(5, 7)] which houses said element forming a reservoir [(1)], and providing mechanical resistance[, especially to pressure,] of the syringe,

wherein said support or casing forms a peripheral shell surrounding an external surface of said element forming a reservoir with virtually zero clearance.--

Claim 46 has been amended as follows:

--46. (amended) The syringe as claimed in claim [44] 45, prefilled with a dose to be entirely delivered.--

Claim 47 has been amended as follows:

--47. (amended) The syringe as claimed in claim [44] 45, characterized in that the base [(4)] is introduced into one end of the reservoir [(1)].--

Claim 49 has been amended as follows:

--49. (amended) The syringe as claimed in claim [48] 45, [characterized in that] wherein the element [or] for forming a reservoir [(1)] is cylindrical and introduced and locked inside a hollow body [(5)] consisting of said support or casing, which provides the protection and the mechanical resistance[, especially to pressure,] of said syringe.--

Claim 50 has been amended as follows:

--50. (amended) The syringe as claimed in claim [44] 49, [characterized in that] wherein said cylindrical reservoir [(1)] is a straight hollow tube having constant internal and external diameters.--

Claim 51 has been amended as follows:

--51. (amended) The syringe as claimed in claim 50, [characterized in that] wherein the internal diameter of the reservoir [(1)] is close to or even equal to that of the internal bore of the needle [(3)] which extends the reservoir.--

Claim 52 has been amended as follows:

--52. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein a uniform conical or funnel-shaped narrowing is provided toward [that] an end of the reservoir [(1)] which houses the needle.--

Claim 53 has been amended as follows:

--53. (amended) The syringe as claimed in claim [44] 45, [characterized in that the] wherein an internal diameter of the needle [(3)] is between 0.2 and [1.2 o] 1.5 mm and [in that the] an internal diameter of the reservoir [(1)], and therefore the diameter of the piston [(2)] of the syringe, is between 0.2 and 5 mm.--

Claim 54 has been amended as follows:

--54. (amended) The syringe as claimed in claim 53, [characterized in that the] wherein a stroke of the piston [(2)]

has a maximum length of 7 cm in order to inject volumes of from 1 [to 10] µl [and] up to [500 µl or] 1 ml.--

Claim 55 has been amended as follows:

--55. (amended) The syringe as claimed in claim 53, [characterized in that the] wherein an external diameter of the reservoir [(1)] is standardized[, especially] to 6 mm, thereby allowing the aforementioned various internal diameters to be provided.--

Claim 56 has been amended as follows:

--56. (amended) The syringe with a tubular reservoir as claimed in claim 50, [in which] wherein the reservoir [(1)] consists of two tubes [(1, 32)], one placed in the other, so as to increase the resistance to internal pressure.--

Claim 57 has been amended as follows:

--57. (amended) The syringe with a tubular reservoir as claimed in claim 50, [in which] wherein the tubular reservoir [(1)] consists of two or more tubes [(27, 28)], one placed behind the other, which are held in this position by the casing, [in particular] for facilitating the formation of syringes allowing the administration of different volumes.--

Claim 58 has been amended as follows:

--58. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein the casing [(5, 7)] consists of two elements, one [(5)] of which forms a hollow body into which the element forming a reservoir is introduced and the other

[(7)] of which contains the hollow body and traps the reservoir, [one of the elements (7)] said other element leaving an opening for passage of a piston rod [(9)] and [the other] said one element leaving an opening for passage of the needle [(3)].--

Claim 59 has been amended as follows:

--59. (amended) The syringe as claimed in claim 58, [characterized in that] wherein the opening in said [second casing] other element [(7)] forms a guide for a piston rod [(9)] having a diameter approximately equal to the internal diameter of the reservoir.--

Claim 60 has been amended as follows:

--60. (amended) The syringe as claimed in claim 59, [characterized in that] wherein the [second] other element [(7)] includes gripping means or finger rests [(8)].--

Claim 61 has been amended as follows:

--61. (amended) The syringe as claimed in claim [44] 57, [characterized in that] wherein means are arranged, on one of said first [or] and second [element (5, 7)] elements, so as to gear down the injection force or to replace the manual force with a means of mechanical or driving assistance [or any other driving means, especially a gas, spring or electromechanical means].--

Claim 62 has been amended as follows:

--62. (amended) The syringe as claimed in claim 61, [characterized in that] wherein the opening in said [second] other element [(13)] is threaded in order to engage with a thread

[(15)] on the piston rod so as to allow helical movement of said rod.--

Claim 63 has been amended as follows:

--63. (amended) The syringe as claimed in claim 61, [characterized in that] wherein said [second] other element [(16)] has a peripheral thread onto which an internally threaded bush [(17)] having a central piston rod [(18)] is screwed.--

Claim 64 has been amended as follows:

--64. (amended) The syringe as claimed in claim 45, [characterized in] wherein said element forming a reservoir [(1)] and the needle [(3)] are assembled, at a needle base [(4)], without any bonding, clip-fastening or any other positive assembly means, ensuring assembly, and resistance to the forces tending to disassemble [its] components of the element forming a reservoir, by means of said casing [(5, 7)], said casing being designed to prevent axial separation of the reservoir [(1)] away from the needle [(3)].--

Claim 65 has been amended as follows:

--65. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein the piston [(2)], which [may or may not be fastened] is fastened to a piston rod [(9, 15, 18)], has a shape which makes it possible to minimize the resistance to flow and which matches the base [(4)] of the needle or that end of the reservoir on the same side as the needle so as

to leave as small an unused volume as possible when the piston [(2)] reaches [its] an end-of-injection position.--

Claim 66 has been amended as follows:

--66. (amended) The syringe as claimed in claim [44] 45, forming part of a set of syringes having a constant diameter and a constant length of the reservoir tube [(1)], making it possible to use the same casing [(6, 7)] for reservoirs provided for [the] an entire range of formulation doses.--

Claim 67 has been amended as follows:

--67. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein the base [(4)] of the needle and the piston [(2)] are made of the same material[, especially stainless steel].--

Claim 68 has been amended as follows:

--68. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein, in order to avoid the risk of injection into a vessel, the syringe includes means [(46, 47, 48)] which make it possible to check whether any blood has been withdrawn from a vessel, this being achieved without having to pull on the piston.--

Claim 69 has been amended as follows:

--69. (amended) The syringe as claimed in claim 68, [characterized by] wherein said means is a catheter needle allowing blood to be withdrawn by the capillary effect as far as a region open to the outside.--

Claim 70 has been amended as follows:

--70. (amended) The syringe as claimed in claim [44] 45, [characterized in that it has] further comprising a passage, comprising a region [(46, 49)] visible by the operator, which communicates with the internal bore of the needle and allows, by one of pressure, capillary effect [or] and vacuum, blood to be seen should the needle have penetrated a vascular lumen.--

Claim 71 has been amended as follows:

--71. (amended) The syringe as claimed in claim 70, [characterized in that] wherein, should blood be removed by capillary effect, provision is made for the internal bore of the needle to communicate with the external atmosphere via a path [(46, 48, 49)] providing a pressure drop such that a flow of air is allowed, while the flow of blood is limited, but that any substantial flow of the semi-solid formulation is unable to take place.--

Claim 72 has been amended as follows:

--72. (amended) The syringe as claimed in claim [44] 45, [characterized in that the] wherein a passage for the blood from the needle [(3)] passes via the reservoir [(1)] and includes an elongate pressure-drop path [(46)].--

Claim 73 has been amended as follows:

--73. (amended) The syringe as claimed in claim 72, [characterized in that] wherein said elongate path [(26)] is between a thread or groove on the base [(4)] of the needle and a

complementary surface in the transparent wall of the reservoir [(1)], or vice versa, this thread [(4)] communicating at [its] an end, directly or through a display region, with the external atmosphere via a small-diameter hole [(48)].--

Claim 74 has been amended as follows:

--74. (amended) The syringe as claimed in claim 70, [characterized in that] wherein the inside of the needle and of the reservoir is maintained under vacuum so that a withdrawal of blood will, by pressure difference, emerge in a display region.--

Claim 75 has been amended as follows:

--75. (amended) The syringe as claimed in claim 74, [characterized in that it includes] further comprising a display region not communicating with the atmosphere.--

Claim 76 has been amended as follows:

--76. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein the needle is covered by a cap [(52)], a package [(54)] or other flexible protection element which isolates [it] the needle from the outside and which will be transpierced by the needle at the moment of injection, this cap, package or protection element being one of retractable, deformable [or] and foldable in order to move away during penetration of the needle and to permit penetration of all or most of the length of the needle.--

Claim 77 has been amended as follows:

--77. (amended) The syringe as claimed in claim 76, [characterized in that the] wherein an inside of the syringe is under vacuum.--

Claim 78 has been amended as follows:

--78. (amended) The syringe as claimed in claim 76, [characterized in that] wherein said package consists of a tube [(52)] or a sachet [(54)] made of plastic, sealed around [the needle (3)] or onto the [latter] needle.--

Claim 79 has been amended as follows:

--79. (amended) The syringe as claimed in claim 78, [characterized in that] wherein said package [(52)], which completely isolates the needle [(3)] from the outside is sealed at the end of the needle[, especially by heat sealing,] so as to completely close off the end of the needle in the manner of a plug.--

Claim 80 has been amended as follows:

--80. (amended) The syringe as claimed in claim 76, in which any withdrawal of blood, being withdrawn by capillary effect, may be seen, [characterized in that] wherein the hole connecting the pressure-drop passage to the external environment emerges, in fact, inside this package so that no communication actually exists between a non-sterile atmosphere and the inside of the needle.--



CHERIF CHEIKH et al. S.N. 09/787,508

Claim 81 has been amended as follows:

--81. (amended) The syringe as claimed in claim 76, [characterized in that] wherein said cap, package or protection element is fixed to [the] a front end of the reservoir [(1)].--

Claim 82 has been amended as follows:

--82. (amended) The syringe as claimed in claim 45, [characterized in that] wherein the prefilling is such that the volume of the formulation occupies the entire space between the piston and the needle without it being necessary to purge the syringe before injection.--

Claim 83 has been amended as follows:

--83. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein the piston [(2)] is not fastened to the piston rod and is pushed back by the [latter] piston rod in the injection direction.--

Claim 84 has been amended as follows:

--84. (amended) The syringe as claimed in claim [44] 45, [characterized in that] wherein a seal [(8)] is interposed between the reservoir [(1)] and the casing [(5, 7)] in order to prevent any communication with an interstice located between the reservoir and the casing [(5, 7)].--

Claim 85 has been amended as follows:

--85. (amended) A process for filling a syringe as claimed in claim [44] 45, [in which] wherein a filling nozzle is connected to said tube or reservoir [(1)], plugged by said piston

[(2)] or by a septum, and in which said piston [(2)] is displaced by the filling of the formulation, said tube then being plugged by said base [(4)] of the needle.--

Claim 86 has been amended as follows:

--86. (amended) The filling process as claimed in claim 85, [in which] wherein said tube is packaged beforehand in a package and in which it is plugged by introducing it into the hollow body of said casing containing the needle and carrying the cap, all of this being inside a second package.--